



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,938	09/29/2003	Jonathan MacGregor Keith	DAVI199.003C1	1824
20995	7590	12/22/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			NEGIN, RUSSELL SCOTT	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/673,938

Applicant(s)

KEITH ET AL.

Examiner

Russell S. Negin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/29/03, 2/12/04, 4/12/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 24, and 26, drawn to a method for deducing the sequence of a target subunit and computer programs therefor, classified in class 702, subclass 19. If this group is chosen, the below mentioned election(s) of species are required.
- II. Claims 6-23, 25, and 27, drawn to a method for deducing the sequence of a primary subunit sequence and computer programs therefor, classified in class 702, subclass 19. If this group is chosen, the below mentioned election(s) of species are required.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related process. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the additional features of primary and secondary sequences make Invention II distinct from Invention I. By using the terms "primary" and "secondary," the applicant is prioritizing between

Art Unit: 1631

sequences to be matched; such prioritizing does not exist in Invention I. Such a limitation imposes an additional search burden.

Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention II, restriction for examination purposes as indicated is proper.

***Specie Election for Group I:***

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of subunit sequence:

Specie I-A: amino acid sequences. (Claim 4)

Specie I-B: nucleic acid sequences. (Claims 4 and 5)

Generic to I: Claims 1-3, 24 and 26

Justification: Each subset of subunit sequences is distinct because each set of macromolecules has a different subunit molecular composition. Searching both protein and nucleic acid subunits impose an additional restriction on the searching because the search for each set of macromolecules is not coextensive.

***Specie Election for Group II:***

This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant must choose one specie from each category.

Category #1:

Species of subunit sequence:

Specie II-A: amino acid sequences. (Claim 18)

Specie II-B: nucleic acid sequences. (Claims 18 and 19)

*If this specie (Specie II-B) is chosen, applicant must also choose from the means of mutagenized nucleic acid sequences as dictated by claims 20-23, which are dependent from claim 19.*

**SUBSPECIES ELECTION THAT IS REQUIRED IF SPECIE II-B ELECTED:**

Specie II-B1: mutagenized by incorporation of nucleotide analogs (Claim 20)

Specie II-B2: mutagenized by incorporation of nucleotide analogs from dPTP or oxo-dGTP (Claim 21)

Specie II-B3: mutagenized by using low fidelity nucleic acid amplification reaction and an error prone DNA polymerase (Claim 22)

Specie II-B4: mutagenized using a repair deficient host (Claim 23)

Generic to category #1: Claims 6-17, 25, 27

Justification: Each subset of subunit sequences is distinct because each set of macromolecules has a different subunit molecular composition. Searching both protein and nucleic acid subunits impose an additional restriction on the searching because the search for each set of macromolecules is not coextensive.

Category #2:

Species of said alternate reconstruction:

Art Unit: 1631

Specie II-C: optimizing alignment of a primary subsequence with another subunit.

(Claim 10)

Specie II-D: comprises optimizing alignment scoring of a primary subsequence with another subunit. (Claim 11)

Generic to category #2: Claims 6-9, 12-23, 25, and 27

Justification: The additional feature of alignment scoring in Claim 11 makes it distinct from the method of Claim 10, which does not require an alignment score. This extra "alignment score" produces an additional search burden as the searches for each of the two species is not coextensive.

Category #3:

Species of subunit mutagenesis:

Specie II-E: The secondary subunit sequence is produced by mutagenesis of the primary subunit sequence. (Claims 14, 16)

Specie II-F: The secondary subunit sequence is produced by mutagenesis of another secondary subunit sequence. (Claims 15, 17)

Generic to category #3: Claims 6-13, 18-23, 25, 27

Justification: The origin of the mutagenized sequence is different in each case: primary and secondary mutagenized sequences as an origin have different, distinct features requiring additional search burdens because the search for each group is not coextensive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Ardin Marschel, Ph.D., Supervisory Patent Examiner, can be reached at (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

-RSN 12/19/05

*RLR 12/19/05*

*John S. Brusca 19 December 2005*  
**JOHN S. BRUSCA, PH.D.**  
**PRIMARY EXAMINER**